

CONDITIONAL PETITION FOR EXTENSION OF TIME

If entry and consideration of the amendments above requires an extension of time, Applicants respectfully request that this be considered a petition therefor. The Assistant Commissioner is authorized to charge any fee(s) due in this connection to Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

REMARKS

Applicants respectfully request reconsideration and allowance of this application in view of the amendments above and the following comments.

Claim 7 has been amended to incorporate specific language from independent claim 1, which, hopefully, will make clearer the departure from the cited art. New claim 11 is added which is supported by the instant example. Applicants respectfully submit that new claim 11 does not introduce new matter. An early notice to that effect is earnestly solicited.

Claims 1-5 and 7-10 were objected to because of alleged informalities. In response, Applicants respectfully submit that the phrase the Examiner quotes under point 3 on page 2 of the Office Action does not, in fact, appear in clause c) of claim 1. Instead, clause c) of claim 1 actually states: "within a constituent region of a *section* of said tissue sample." A close examination of the amendment of April 23, 2007, will reveal that the word "section" is not stricken.

Claims 1, 2, 4, 5, 8 and 9 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3 and 4 of copending USSN 10/022,618. In response, Applicants respectfully renew their previous request that this issue be held in abeyance until allowable subject matter is indicated, at which time Applicants will take appropriate action, for example, file a suitable terminal disclaimer or prove patentable distinctness.

Claims 1, 2, 5, 9 and 10 were rejected under 35 USC § 102(b) as being anticipated by Rao et al. ("Rao"), *Cancer Epidem. Biomarkers & Prevention*, 7: 1027-1033 (1998). In response, Applicants respectfully submit that Rao does not anticipate the present claims. The instant claims require that the individual signal intensities are combined and accredited and then the *combined and accredited signal intensities* are compared to the threshold value. Nowhere does Rao carry out such an operation. The thresholds that Rao reports at the bottom of page 1029 are for the *individual* marker intensities, *not* for any combined and accredited signals. Therefore, Rao cannot anticipate the present claims.

As previously pointed out, the pitfall of Rao is shown in Table 1 on page 1029. Samples 12 and 27 have no cancer but are found positive for two markers. On the other hand cancer Samples 46 and 55 only show a positive signal for just one marker.

In view of the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw this rejection. An early notice that this rejection has been reconsidered and withdrawn is earnestly solicited.

Claims 1, 3-5 and 8-10 were rejected under 35 USC § 102(b) as being anticipated by McNamara et al. ("McNamara"), US 6,007,996. In response, Applicants respectfully submit that McNamara suffers from the same defects as Rao. Thus, McNamara also does not comparing the combined and accredited signal intensities to a threshold value to indicate the presence of cancer cells or their precursors in the cell sample or tissue sample. As discussed, for example, in McNamara at column 30, lines 31-35, McNamara is able to extract from the combined signal the values of the *individual* signals. The *combined* signal is *not* compared to a threshold value to give an indication of the presence of cancer cells or precursor cells in the

cell sample or tissue sample. Consequently, McNamara also cannot, as a matter of law, anticipate the present claims.

In view of the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw this rejection as well. An early notice that this rejection has also been reconsidered and withdrawn is earnestly solicited.

Claim 7 was rejected under 35 USC § 102(b) as being anticipated by Bacus et al. ("Bacus"), US 5,109,429. In response, Applicants have amended claim 7 in a manner that should make clear to the Examiner the novelty of claim 7 in view of Bacus. Applicants respectfully submit that Bacus does not teach reagents for the particular combination of molecular markers required by claim 7; nor protocols for carrying out the method of claim 1. As a result, Bacus cannot anticipate claim 7.

Claim 7 was rejected under 35 USC § 103(a) as being obvious over Rao or McNamara in view of Bacus. In response, Applicants point out that this rejection was premised on Rao or McNamara anticipating claim 1, which has been shown above to be incorrect. Therefore, Applicants respectfully submit that this rejection should be reconsidered and withdrawn as well. Nothing in Bacus alone or in combination with either Rao or McNamara bridges the clear gaps between Rao or McNamara and the instant claims. Consequently, the combination of Rao or McNamara and Bacus does not make out a *prima facie* case of the obviousness of claim 7.

In view of the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw this rejection as well. An early notice that this rejection has also been reconsidered and withdrawn is earnestly solicited.

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,
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